Anonymous donor sperm banking has been a fundamental aspect of reproductive medicine for several decades. In 1987, >170 000 women in the USA were treated for infertility using artificial insemination. Current estimates suggest that the number of women seeking treatment for infertility has increased markedly since that time; however, there are no accurate, updated data to indicate the magnitude of that increase. Most anonymous donor sperm banks in the USA can be categorized as one of three types based upon administrative structure: (i) physician practice based; (ii) hospital/clinic based; or (iii) commercial corporations. Of these it is estimated that the most common structures are the physician office and hospital/clinic based banks. However, the largest (i.e. those processing the most units) are the for-profit corporate banks. A survey conducted in 1989 found that there were at least 135 sperm banks operating in the USA. More recent information indicates the number of banks to be somewhere between 50 and 150. Guidelines for anonymous donor sperm banking practices have been established by the American Society for Reproductive Medicine and standards have been established by the American Association of Tissue Banks (AATB). The AATB has recently established an inspection and accreditation programme and six anonymous donor banks have been accredited in the last few years. It is anticipated that mandatory registration of all donor banks will be required by the FDA in the near future with mandatory inspection and accreditation to follow shortly thereafter.

Key words: human semen banking/survey/USA

Introduction

Although human semen banking and artificial insemination with anonymous donor sperm (therapeutic donor insemination; TDI) has been a standard infertility treatment modality for over three decades, changes in medical, social and legal aspects have transformed this practice in the USA over the last 7–10 years (Critser and Linden, 1995). Primary among the forces driving this change was the realization that semen can serve as a vector in the transmission of human immunodeficiency virus (HIV) in the late 1980s. While it had long been known that semen is a vector for numerous ‘sexually transmitted diseases’, these were mostly treatable, non-life-threatening conditions and their consequences were not considered prohibitive in the benefit/risk approach to utilizing methods which had been established through years of practice.

However, with the recognition of the risk of HIV transmission, clearly the practice of TDI as ‘usual’ was no longer an option (Linden and Critser, 1995). In the years shortly following 1985, the ability to test for HIV became available. Several USA based professional societies, e.g. the American Association of Tissue Banks (AATB), the American Society for Reproductive Medicine (ASRM)) and some state governments, e.g. New York and Indiana, issued guidelines (ASRM), standards (AATB) and regulations (New York and Indiana) requiring the exclusive use of cryopreserved human spermatozoa which must be quarant-
ined for at least 180 days and not released without two negative serological results, 180 days apart, for potential pathogens including HIV.

Concurrent with the change in the way in which human semen samples were banked and distributed came a overall change in the USA tissue banking community reflecting similar issues and modifications. These events subsequently triggered both reflection and reaction, resulting in a cascade of events which progressively increased the level of infectious disease screening stringency and, at the same time, increased the level of paperwork required (e.g. policies and procedures manuals for new activities, additional records associated with storage, inventory during quarantine and subsequent placement into non-quarantine storage) and hence the administrative burden with associated increased costs. In general, and consistent with this pattern of continuous development of increased regulation of tissue banking activity, the US Food and Drug Administration (FDA) announced the immediate regulation of most aspects of tissue banking in December 1993, but specifically excluded reproductive cell types from that ruling. However, it is anticipated that this exclusion will be rescinded in the near future and currently there are ongoing discussions to that effect.

Given this brief discussion regarding recent developments in regulatory activity in the USA, it is fair to say that of the two primary concerns commonly held by administrative governing agencies, namely safety and efficacy, safety is relatively well addressed. However, this is not as true for issues related to efficacy. Again, to date, efforts have focused upon minimizing the risk aspects of the TDI procedure, although little has been done to monitor or increase the benefit aspects of this treatment. In fact, it is the case that accurate measures of efficacy (e.g. fecundity) are generally unknown. Although they may be reported on a physician practice-by-practice basis or, more commonly, as the result of academic reproductive medicine clinical trials; a comprehensive measure of outcomes on a semen bank basis remains largely unknown and/or unreported (Steele et al., 1995).

Therefore, as the TDI situation moves forward from this point in time; the focus will need to shift to developing improvements in the area of efficacy as well as safety. As with the history of safety concern, this evolution may well take root through voluntary professional peer groups and their societies (e.g. AATB, ASRM) and then be transferred in concept to the governmental agencies (e.g. the FDA) for uniform application as a mandate either as they become more mature or in the event of high level public concern. In this context, the potential to establish a sub-division within the FDA to deal specifically with the unique aspects of reproductive cell and tissue banking [similar to the Human Fertilisation and Embryology Authority (HFEA) in the UK], would seem particularly timely and a useful approach. A parallel movement, now rapidly gaining momentum in the USA, which will likely influence an increased interest in efficacy, is the issue of ‘Health Care Reform.’ One of its cornerstone tenets is the cost of the application of effective procedures based upon critical outcomes measures. Within this context, the cause likely to effect change in this direction will be the so-called ‘Third-party-payors’, the insurance companies and the Heath Management Organizations (HMOs) willingness to reimburse only for medical procedures which are highly effective.

All of this is superimposed against a background in which the Obstetrics and Gynaecology/Reproductive Endocrinology physician practices continue to have an increasing number of infertile patients. This is due, at least in part, to couples waiting until they are older before attempting to establish families (Office of Technology Assessment, 1988). Therefore, the need for available, safe and effective, human semen samples for TDI is likely to continue or increase over the next few years.

Current status of semen banks in the USA
A survey of major semen banks in the USA was conducted by the AATB in early 1995 (J.K.Critser, unpublished; presented at the 1995 meeting of the British Andrology Society). The aim of the survey was to capture both the current status of human semen banking in the USA as well as develop an understanding of where this industry might be evolving in the near future. The survey in its entirety is shown in Appendix 1. In addition to the information collected from the survey, additional
Current status of USA semen banking

Table I. USA sperm banks (taken from Olson, 1995)

<table>
<thead>
<tr>
<th>Year reported</th>
<th>No. banks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1964</td>
<td>3</td>
</tr>
<tr>
<td>1969</td>
<td>6</td>
</tr>
<tr>
<td>1971</td>
<td>7</td>
</tr>
<tr>
<td>1980</td>
<td>12</td>
</tr>
<tr>
<td>1983</td>
<td>16</td>
</tr>
<tr>
<td>1986</td>
<td>93</td>
</tr>
<tr>
<td>1987</td>
<td>493</td>
</tr>
<tr>
<td>1988</td>
<td>61</td>
</tr>
<tr>
<td>1989</td>
<td>135</td>
</tr>
<tr>
<td>1990</td>
<td>42</td>
</tr>
<tr>
<td>1994</td>
<td>451</td>
</tr>
</tbody>
</table>

data were obtained from a directory of USA sperm banks (National Research Group Sperm Bank Directory, 1994). From these two sources, the following picture can be presented regarding the status of USA based semen banks providing anonymous donor samples in 1995.

Number of semen banks in the US

It should be noted that those currently in the field agree that there is no accurate total of how many semen banks are operating in the USA. Certainly the 92 banks captured from the sources indicated above do not necessarily represent all of the banks in the USA which provide anonymous donor samples. There are many other operations which also provide other semen bank activities (e.g. client depositor samples processing and storage). The existence of these two major categories of semen banks (i.e. those providing anonymous donor samples and those proving other services) continue to present a problem in accurately identifying the true number of semen bank operations in the USA. In addition, it is widely accepted that there are many, relatively small semen banks operating as part of either physician practices or University medical systems; these are most often omitted from estimates of the total number of semen banks in operation.

An example of the magnitude of this problem is shown in Table I. These data are drawn from a recent presentation (Olson, 1995) and were intended to highlight this concern. From Table I it can easily be seen that the criteria used to identify semen banks have varied widely, making interpretation of such data extremely difficult. For example, it is highly unlikely, as suggested by the data in Table I, that the number of semen banks in the USA increased by 400 (93 to 493) in 1987 and subsequently decreased by an even greater number the following year (493 to 61).

The figure of 135 semen banks in 1989 comes from an earlier survey conducted by J.K. Critser and N. Ruffing (unpublished data; presented at the 1989 Annual Meeting of the American Society for Andrology). This number is derived from banks identified as those providing anonymous donor samples. The existence of a more-or-less bimodal distribution of number of semen banks is likely to represent the two categories of banks: (i) those providing, at least, anonymous donor samples and (ii) the sum of category 1 plus those banks which do not provide anonymous donor samples. Based upon this hypothesis, it is likely that the number of banks in the first category is somewhere between 50 and 150; while the number in the second category is likely between 350 and 450. However, even these estimates may not account for the many assisted reproduction laboratories providing in-vitro fertilization (IVF) and related services. Most of these programmes provide some form of semen cryopreservation and if added to these numbers, might add an additional 200–300 programmes to the total number.

Survey results

Distribution of USA semen banks

The results of the 1995 AATB survey are shown in the following series of figures. Figure 1 diagrammatically shows the number and distribution of semen banks providing anonymous donor samples identified in the survey. This figure shows that there is at least one such semen bank in each of the 50 states except: Alabama, Alaska, Delaware, Hawaii, Idaho, Iowa, Maine, Mississippi, Nevada, New Hampshire, North Dakota, Rhode Island, South Dakota, and Vermont. Among those states with anonymous donor semen banks, two, Texas and California, have more than 10 banks each.

Time semen banks have been in operation

Figure 2 shows the founding year for those 36 banks reporting this information. Of these 36
Figure 1. Number of USA sperm banks, by state.

Figure 2. Founding dates of USA sperm banks.

Figure 3. Number of donors in USA sperm banks.

banks, only two (6%) have been in existence for >25 years; while 15 of the 36 (42%) have been in operation for at least 10 years. The sharpest increase in semen banks occurred during the years between 1986 and 1989 (13 of the current 36; or 36%). This is of interest, as this is temporally coincident with the change in practice away from use of non-cryopreserved/quarantined samples to exclusive use of cryopreserved/quarantined samples due to the realization of the risk of HIV transmission.

Anonymous semen donors

Figure 3 shows the number of anonymous donors participating in the USA-based banks. Of the 33 banks responding to this question, 16 (48%) had fewer than 20 active donors; while only two (6%) had 100 or more active donors. Figure 4 shows the percentage of applicant donors for the anonymous donor programmes which are accepted into those programmes. Of the 35 responding banks, 11 (31%) accept 5% or fewer of the applicants, while 24 (68%) accept 10% or fewer. However, two (6%)
accept 50–60% of applicants. Figure 5(a and b) shows the distribution of minimum and maximum age criteria for USA anonymous donors. No banks accept donors aged <18 years. Many individual state statutes define the minimum age to participate in programmes at 18 years of age and 76 of 91 (84%) banks have this as their minimum age, with six banks indicating a minimum age criteria of 21 years. A much wider distribution is found for maximum age criteria, ranging from as low as 24 years of age to a high of 50 years. However, 50 out of 91 (55%) banks set an upper age limit at 35 years and another 25 (27%) set this at 40 years. These upper age limits ages 35 and 40 are those recommended by the AATB and American Society for Reproductive Medicine (ASRM) respectively. Figure 6 shows the distribution of reimbursement provided to semen donors for each ejaculate. The modal value is $50; with a low of $0 and a high of $150.

**Distributed semen sample characteristics**

Figure 7 shows the distribution of the number of motile spermatozoa in each unit of anonymous semen samples for distribution. Of the 35 banks providing information, only one (3%) bank provides 10×10^6 motile spermatozoa or less, 16 (46%) provide 15–20×10^6 motile spermatozoa and 17 (49%) provide 25–40×10^6 motile spermatozoa; one (3%) bank provides a minimum of 60×10^6 motile spermatozoa. The various total volumes of these samples is shown in Figure 8. Of 35 banks,
(sperm banks) = 35
mean % = 26

Figure 7. Number of motile spermatozoa per unit.

Figure 8. Volume of sample provided.

Figure 9. Amount charged (US$) per unit.

16 (48%) provide samples with a volume of 1.0 ml; while 13 (37%) utilize volumes <1.0 ml and six (17%) use volumes >1.0 ml. It should be noted that some banks describe their units in terms of the sperm concentration per ml, but distribute units with <1.0 ml. Figure 9 shows the amount (in US$) charged for the distribution of each anonymous donor semen sample. These values range from a low of $70 to a high of $205; with a mean value of $129 and a modal value of $120.

Number of anonymous donor units distributed in the USA per year

Figure 10 shows the distribution of the number of units of anonymous donor semen distributed in 1992–1994. Panels a and b show these values for 1992 and 1993 respectively. These graphs appear to show multiple populations. Of 34 banks, 14 (41%) reported 500 or fewer units distributed in each of those 2 years; ~11 (32%) banks distributing 800–1500 samples; a third group of three (9%) distributing 2500–5000 and a fourth group of six (18%) distributing ≥5000 units per year. In 1994 this general pattern appears to have continued, with an overall increase in the total number of samples distributed and perhaps the development of three rather than four groups: (i) 14 (41%) distributing 100–600 units; (ii) 11 (32%) distributing 800–2500 units and (iii) nine (26%) distributing 4000–5000+. The overall general trend from 1992–1994 is shown in Figure 11. The 34 reporting banks indicated that collectively they distributed: 83309, 85446 and 90312 units in 1992, 1993 and 1994 respectively.

The survey questionnaire also asked the respondents to estimate what they thought was the likely current (1994) values for both: (i) the total number of units distributed from all USA semen banks and (ii) the total demand for donor samples in the USA. A total of 28 banks estimated the total number of units distributed (Figure 12). These estimates ranged from a low of 10 000 units/year (a figure much lower than already accounted for by the banks responding to the survey, >90 000) to a high of >300 000/year. This upper estimate is generally consistent with a simple linear extrapolation, assuming ~100 banks (90 000/year, from 34 banks, times 3 (34×3, or 112 banks), would yield ~270 000 units/year). In all, 23 banks ventured estimates of the total demand for anonymous donor samples (Figure 13). These values corre-
sponded directly with the estimates of the total number of units distributed; indicating that the respondents thought that 'supply and demand' were in equilibrium.

**US semen banking standards, guidelines and regulations in 1995**

If a single term had to be chosen to describe the current state of semen banking in particular and
tissue banking in general in the USA in 1995, it might very well be ‘regulation’. For a variety of historical reasons related to the practice of medicine in the USA, many ancillary medical programmes have remained largely unregulated until the very recent past. Clinical laboratory services were inspected and accredited by various agencies; but not until 1988 did the USA federal government pass legislation mandating uniform minimum standards in this area, the so-called Clinical Laboratory Improvement Act of 1988 (CLIA88). (There was an earlier CLIA67; but that only covered laboratories involved with the transport of clinical material across state borders). However, in the last few years, regulations have, appropriately, expanded in number and scope. The three primary sources of standards, guidelines and new evolving regulations involving USA semen banking are briefly described below.

**American Association of Tissue Banks standards**

The AATB has had published standards for semen banking for > 10 years. The current AATB semen banking standards were released in 1992 and a revision of those standards is scheduled to be released in 1995. Although these standards comprehensively address issues related to tissue banking, only those areas pertaining to safety (e.g. donor testing and screening) will be described here. The following are those general areas covered by these standards (taken from the AATB Standards for Semen Banking, 1993). The AATB standards use the following definitions:

**Anonymous donor**: A semen donor whose identity is unknown to the recipient.

**Artificial insemination**: The placement of semen within the body of a recipient or the utilization of semen in another assisted reproductive technology procedure.

**Client depositor**: One who banks his semen for deferred insemination of a sexually intimate partner; he is not a donor.

**Cryobanks**: Facilities that cryopreserve and store cells and tissues.

**Directed donor**: A donor who is known to the recipient (although not necessarily by name in the case of surrogate mother situations) and who directs his semen for use by a particular recipient.

**Donation**: The collection of semen for use by recipients who are not sexually intimate partners of the donor.

**Recipient**: A women undergoing artificial insemination or receiving an embryo from a donor.

**Semen**: The fluid of man’s reproductive system consisting of spermatozoa and secretions of accessory glands.

**Semen Bank**: A facility that collects, processes, stores and/or distributes human semen for use in assisted reproductive technology procedures including, but not limited to, artificial insemination.

**Semen Donor**: One who provides his semen for cryobanking and subsequent artificial insemination of a recipient other than his wife or other sexually intimate partner. A semen donor can be further categorized as a directed donor or an anonymous donor.

**Physical examination and general laboratory testing for sexually transmitted diseases**

According to the AATB standards, an examination must be conducted for indication of sexually transmitted diseases. A test for *Neisseria gonorrhoea* shall be performed on semen or a urethral specimen while urine or a urethral specimen shall be tested for *Chlamydia trachomatis*. Specimens collected during intervals in which *N. gonorrhoea* and *C. trachomatis* infections cannot be ruled out shall be discarded. The test kits utilized must be FDA approved and the manufacturer’s requirements for specimens must be met.

A blood specimen must be drawn to determine the donor’s haemoglobin concentration, white blood cell (WBC) and differential counts. A urinalysis and urine culture shall be performed from a urine specimen. Spermatozoa may not be released from a donor unless results are within predetermined ranges established by the Medical Director and shall be documented in the donor record.

Semen shall be screened for WBC and the number should be less than a maximum predetermined number established by the Medical Director. semen shall be tested for sperm quality and found acceptable prior to issue as measured against criteria set by the Director in consultation, when appropriate, with the Medical Director and Medical Advisory Committee, including such parameters as ejaculate volume and sperm motility, concentration,
morbidity and cryosensitivity. Sperm quality tests shall be repeated at a frequency determined by the Director.

**Social/sexual history**

Semen donors shall be screened to determine their educational and occupational achievements, family background, interests, talents and attitudes as well as their reliability as a potential donor. The donor’s history shall include personal alcohol and drug consumption, the history of sexually transmissible diseases in self and multiple partners and any family history of chemical and radiation exposure.

**Medical history**

Disease screening shall include evaluation for risk of infectious disease, malignancy and neurological degenerative disease. In equivocal situations, a specialist may be consulted. The screening process shall include family medical history and genetic background. Donors exhibiting an infectious skin disease that creates a risk of contamination of the semen shall be excluded. Each semen bank shall establish guidelines for evaluation of other infections.

**Family history and genetic background**

Minimum requirements for donors are that they should not: (i) have or carry any major Mendelian disorder, such as haemophilia, malformation that carries serious functional or cosmetic handicap; (ii) be heterozygous for an autosomal recessive gene known to be prevalent in the donor’s ethnic background and for which heterozygosity can be detected. This includes α-thalassemia, β-thalassaemia, sickle cell disease, Tay–Sachs disease, glucose 6 phosphate deficiency and cystic fibrosis; (iii) have or have had in the past any major malformation of complex cause (multifactorial/polygenic) such as spina bifida and heart malformation; (iv) have or have had in the past any familial disease with a major genetic component, such as severe hypertension; and finally, (v) be a carrier of a chromosomal rearrangement that may result in unbalanced gametes.

**Family history and genetic background: first degree relatives**

On the basis of a family history, the donor’s first degree relatives (parents and offspring) should be free of: (i) major malformations of complex cause (multifactorial/polygenic), such as spina bifida or heart malformations; (ii) major Mendelian disorders that fall into one of three categories: firstly, autosomal dominant or X-linked disorders in which age of onset extends beyond the age of the donor, such as Huntington’s disease, unless gene detection is available and donor is negative. Secondly, autosomal dominant inheritance with reduced penetrance, unless gene detection is available and donor is negative. Thirdly, autosomal recessive inheritance, unless a carrier detection is available and donor is negative; (iii) syndromes resulting from a chromosomal abnormality (such as Down’s syndrome), unless the donor has a normal karyotype.

**Additional testing of living donors**

All donor samples must be quarantined for a minimum of 6 months. After such time and prior to release of the semen for use in artificial insemination, the donor shall be retested for evidence of HIV-1, HIV-2, HTLV-1, HCV and for anti-HBV. All tests for infectious disease, including those for N. gonorrhoea shall be repeated at least every 6 months while the donor remains active.

**Age criteria: semen donors**

Age of semen donors shall be younger than 40 years of age to minimize the risk of genetic anomalies except with the written agreement of the user physician.

**American Society for Reproductive Medicine Guidelines**

The ASRM released guidelines for gamete donation in 1990. These have been revised and the current ASRM guidelines were published in 1993. The following are general areas and issues covered by these guidelines (taken from The American Fertility Society Guidelines, 1993).

**General criteria**

Semen donors must be of legal age (18–21) and no older than 40 years of age. A complete sexual history/exclusion for high risk factors. A complete physical exam including evaluation for urethral discharge, genital warts/ulcers, blood type and Rhesus factor must be performed.
Genetic screening of sperm donors
Semen donors should: (i) be generally healthy and should not have (had) any major Mendelian disorders; (ii) not be heterozygous for an autosomal recessive gene known to be prevalent in the donor’s ethnic background and for which heterozygosity can be detected; (iii) not have (had) any major malformation of complex cause (e.g. spina bifida or heart malformation); (iv) should not have (had) any familial disease with a major genetic component (e.g. severe hypertension); (v) not carry a chromosomal rearrangement; (vi) be young (up to 40 years of age for sperm donors); (vii) donor’s first degree relatives should be free of: a) major malformations. b) major Mendelian disorders in the following categories: i) autosomal dominant or X-linked disorders (e.g., Huntington’s), ii) autosomal dominant inheritance, iii) autosomal recessive inheritance if the disease has a high frequency in the population and iv) a chromosomal abnormality, unless the donor has a normal karyotype.

Additional testing of living donors
All donors must be tested for: HIV-1, HIV-2, HBV(sAG), CMV (IgG), syphilis, Neisseria gonorrhea (semen or urethral culture), Chlamydia (urethral or urinary). Semen samples must be quarantined for 180 days with retesting for HIV-1, HIV-2 with negative results before release.

Food and Drug Administration proposed regulations
In December, 1993, the US FDA released an interim rule announcing their immediate regulation of human tissue banking operations (FDA Interim Rule, 1993b). That 1993 rule, however, explicitly excluded reproductive cells and tissues (spermatozoa, oocytes and embryos). Recently, in March of 1995, the FDA announced its intention to rescind the exclusion for reproductive cells and tissues and has indicated that the agency will begin regulating this area of tissue banking (e.g. semen banks) under a final rule (FDA, 1995). With this announcement, it appears that semen banking in the USA will abruptly move from an unregulated, voluntary, peer review system, to a federally regulated system.

The following are excerpts of the recent description of the current issues the FDA is considering for inclusion into its final rule which pertains specifically to reproductive cells and tissues (FDA, 1995). This is a partial, edited text, intended to provide a general understanding of the direction that regulation of reproductive cells and tissues is taking in the USA. The reader is referred to the entire text for other important details. The term 'reproductive cells and tissues' has evolved in the USA (through the AATB standard terminology) as the collective term for all reproductive cells and tissues which are, or could potentially be, ‘banked’ in a tissue bank context. The FDA has, in some cases, shortened the term to ‘reproductive tissues’, in part because the issues related to banking sperm, oocytes, and ovarian and testicular tissue are being addressed under the broader umbrella of ‘tissue banking’ in general. These issues will be the subject of ongoing discussions between the FDA and various society and association representatives; but they serve to highlight the general direction in which this process appears to be moving.

Proposed FDA donor testing for reproductive tissue
Testing of reproductive tissue donors should include all tests recommended for human tissue for transplantation. The FDA also believes that donors of human reproductive tissue should be tested for physical evidence of and/or exposure to, communicable diseases that can be transmitted through artificial insemination, fertilization and/or implantation. Tests should include the following: a complete blood count, urinalysis, urine culture, antibodies to HIV-1, antibodies to HIV-2, hepatitis B surface antigen, antibodies to hepatitis C virus, antibodies to human T-cell lymphotropic virus type I, antibodies to CMV, serological test for syphilis, semen white blood cell count, urethral or cervical swab for C.trachomatis, N.gonorrrhea, Mycoplasma hominis and Ureaplasma urealyticum.

The FDA is evaluating donor testing requirements for release from quarantine for semen. FDA is considering a provision that would require, at the time of donation of semen, that the donor be tested. Semen would only be accepted if the donor is negative for all tests and screening. Such donated semen would then be placed in quarantine for 6 months in an appropriate method of storage. After
Current status of USA semen banking

6 months, the donor would be retested for communicable disease serological markers to establish that results are negative. If serological marker test results were negative, the donated semen would be released from quarantine.

Proposed FDA donor screening for reproductive tissue

The FDA believes that screening of reproductive tissue donors should include the taking of a medical history to assure freedom from sexually transmitted diseases (STD), genitourinary diseases and freedom from risk factors for HIV, hepatitis B, and hepatitis C infection. FDA is considering whether donor screening criteria for high risk behavior for exposure to HIV and hepatitis viruses should be adapted for use in screening reproductive tissue donors. FDA believes that reproductive tissue should not be accepted from donors meeting any of the [established 'high-risk' criteria (see full document for details)].

The FDA also believes that tissue should not be accepted from donors with a history of having received within 1 year preceding donation, human blood, blood components or any derivative of human blood (FDA, 1993a) (except in the case of specific immunization of Source Plasma donors (21CFR 640.66)) (FDA Revised Recommendations to Blood Establishments, 1992a,b).

The screening should also include a physical examination to establish that the donor is in good general health and is free from any signs and symptoms of blood-borne infections, systemic communicable diseases, STDs, genitourinary communicable diseases, and any signs and/or symptoms of illegal injectable drug use.

The FDA believes that repeat donors must have a complete donor suitability determination performed every 60 days. For those who donate less frequently than every 60 days, a complete donor suitability determination should be performed with every donation. For repeat donors where <30 days have elapsed, an abbreviated donor suitability determination should consist of all tests indicated in section IIC1, a review and update of the donor medical history obtained at the last donation, and an abbreviated physical examination.

Future developments in USA semen banking

Registry of semen banks

The 1995 FDA proposal concerning the regulation of tissue banks, including semen banks, has in it a provision for the possible registration of tissue establishments. In this regard, the FDA is considering requiring tissue banks to register with the FDA. Such registration would provide a mechanism for the FDA to identify all banks, transmit information to those operations and to monitor them. This kind of federal oversight could also provide a mechanism for the establishment of a central database which could be used finally to answer many of the unresolved issues surrounding USA semen banking, such as how many banks are actually in operation, how many samples are distributed and where do they go? Establishment of such a central database could also provide the basis for finally measuring efficacy of the total TDI system from semen bank to physician practice to patient insemination.

Outcome measures

One of the primary issues currently facing USA semen banks is related to measuring the efficacy of the sample provided in the context of TDI. Historically, semen bank operations have generally been physically distinct from the physician practice where the inseminations occur. This has been problematic because there has been a clear lack of communication between the end-user physician practice, the site at which outcomes can be determined, and the providers of the semen samples, the banks. Before meaningful attempts can be made to collect outcomes data, better communication between physician offices and semen banks in the USA must be established. While there are, to the best of my knowledge, no current plans to address this issue on a national level, many individual semen banks do recognize this matter as an essential problem and have undertaken programmes to facilitate exchange of outcome data from physician practices. If federal (FDA) regulations and required registration of USA semen banks becomes enforced, establishment of a national database may develop and serve to provide the means of both collecting and reporting such information.
Acknowledgements

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Appendix I.
Questionnaire

(1). When was your sperm bank founded? __________

(2). How many locations do you operate? __________

(3). How many active donors do you manage at the current time? __________
   (I know this varies from month to month but a close estimate would be fine)

(4). What is your charge for a unit of cryopreserved sperm? __________

(5). What is the standard total number of motile sperm/unit? __________

(6). What is the standard volume of the sample? __________

(7). What percent of donor applicant are accepted into your program? __________

(8). What are the major impediments to expanding growth of your program?
   (a) Number of Qualified Donors? __________
   (b) Number of Donors with specific genotypic characteristics? __________
   (c) Demand for samples? __________
   (d) Other _________________________________

(9). Approximately how many samples did your program distribute
   in 1992? __________
   in 1993? __________

(10). Approximately how many samples do you project you will distribute this calendar year?
   (1994)? __________

(11). What would you estimate the number of sperm banks in the USA to be? __________

(12). What would you estimate the number of sperm samples distributed per year in the USA to
   be? __________

(13). What would you estimate the demand, in terms of the total number of anonymous donor
   samples needed per year in the USA, to be? __________